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K002096
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4. 510(k) Summary

Submitted by:	The Procter & Gamble Company 6100 Center Hill Avenue Cincinnati, OH 45224
Contact Person:	Mark M. Anderson, Regulatory Affairs Manager (513) 634-5196 (voice) (513) 634-7364 (FAX)
Date Summary Prepared:	7 July 2000
Trade Name:	TAMPAX® Satin Tampons & TAMPAX® Tampons
Common Name:	Menstrual Tampon
Classification Name:	Unscented Menstrual Tampon (per 21 CFR 884.5470)
Predicate Devices:	TAMPAX® Satin Tampons, Procter & Gamble, K924303 & K923932 TAMPAX® Tampons, Procter & Gamble, Preamendment Device & K896989 (labeling)

Device Description: The device is a conventional unscented menstrual tampon consisting of an absorbent pledget, a withdrawal cord, and a flushable paper applicator.

- The absorbent pledget consists of a rectangular pad of layered cotton and rayon fibers. The pad is overwrapped with a non-woven rayon material, and a cotton withdrawal cord is sewn to the pad with cotton thread. The pad is compressed into a traditional bullet-shaped pledget.
- The formed pledget is inserted into a flushable paper applicator consisting of an outer insertion tube and an inner pusher tube. For TAMPAX® Satin Tampons, flexible petals form a closed, rounded tip at the distal end of the outer applicator tube. For TAMPAX® Tampons, the distal end of the outer applicator tube is open.
- Each tampon is wrapped in an individual paper wrapper and packaged in sealed multi-unit containers for retail sale.

Intended Uses: The device is intended to be inserted into the vagina to absorb menstrual fluid.

Technological Characteristics: The device is similar to the predicate devices in terms of component materials, overall design (see *Device Description*,

above), and labeling. This device differs from the predicate devices only in the layered configuration of the absorbent fibers in the pledget. The layered fiber pledget uses the same absorbent materials as the predicate devices in a way designed to enhance the acquisition without decreasing the retention of menstrual fluid.

Non-Clinical Performance: *In vitro* microbiological testing showed no significant differences between layered fiber tampons and non-layered fiber tampons on the growth of representative vaginal microorganisms or on the production of TSST-1 toxin by *S. aureus*.

Clinical Performance: Results of a safety-in-use clinical study showed no significant differences between the layered fiber tampon and a blended fiber control tampon in terms of *in vivo* microbiological parameters (prevalence and count of representative vaginal microflora), mean vaginal pH, vaginal discharge, effects on the vagina or cervix observable by colposcopic examinations, or self-reported incidents of discomfort during the course of the study.

TAMPAX® tampons with layered fibers comply with the requirements of 21 CFR 801.430. Therefore, additional testing of these tampons is not necessary to establish their equivalence to the predicate tampons in terms of effectiveness.

Conclusions: The results of the preclinical and clinical testing of this device demonstrate that it is safe for its intended use and that it is substantially equivalent to the cited predicate devices with regard to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2000

Mark M. Anderson, Ph.D.
Regulatory Affairs Manager
Procter & Gamble Company
Feminine Care Global Business Unit
6100 Center Hill Avenue
Cincinnati, Ohio 45224

Re: K002096
Tampax® Satin Tampons (Closed End Flushable (CEF) applicator)
Junior, Regular, Super, and Super Plus Absorbencies
Tampax® Tampons (Open End Flushable (OEF) applicator)
Junior, Regular, Super, and Super Plus Absorbencies
Dated: July 7, 2000
Received: July 11, 2000
Regulatory Class: II
21 CFR 884.5470/Procode: 85 HEB

Dear Dr. Anderson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

3. Statement of Indications for Use

510(k) Number (if known): K002096

Device Name: TAMPAX® Satin Tampons & TAMPAX® Tampons

Indications for Use:

TAMPAX® Satin Tampons & TAMPAX® Tampons are unscented menstrual tampons that are inserted into the vagina and used to absorb menstrual fluid.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ **OR** **Over-The-Counter Use** ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002096

(Optional Format 1-2-96)

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